REMARKS

Claims 1, 15, 16 and 18-22 are pending in the subject application. Applicants specifically request that the Amendment filed by applicants on December 26, 2006 in connection with the above-identified application, and not entered by the U.S. Patent and Trademark Office as indicated in the Advisory Action issued February 20, 2007, not be entered.

By this Amendment, applicants have amended claim 1 to recite that the antisense oligonucleotide has the sequence of a human Ku70 cDNA or human Ku80 cDNA in the antisense orientation. Claim 15 has been amended to recite that antisense has the sequence of a human Ku70 cDNA in the antisense orientation. Support for both of these amendments can be found in the specification as originally filed at, inter alia, page 83, lines 7 to 16 and Fig. 13. Applicants maintain that the amendments to the claims raise no issue of new matter and respectfully request their entry. After entry of this Amendment, claims 1, 15, 16 and 18-22 will be pending and under examination.

Provisional Obviousness-Type Double Patenting Rejection

The Examiner provisionally rejected claims 1, 15, 16 and 18-22 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 27, 39 and 40 of copending U.S. Application No. 10/712,642.

Applicants understand that this is only a provisional rejection, and will consider filing a Terminal Disclaimer if necessary should the rejection become non-provisional.

Rejection under 35 U.S.C. §102(b)

In the June 26, 2006 Final Office Action, the Examiner rejected claim 15 as allegedly anticipated by Takiguchi et al. (Genomics, 35:129-135, 1996) in part because "the oligonucleotides disclosed by Takiguchi et al. meet all of the structural limitations of the instantly claimed invention...".

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, and without conceding the correctness of the Examiner's position, applicants have herein amended independent claim 15, from which claims 16 and 18-22 depend. Applicants note that, as amended, claim 15 is directed to an antisense oligonucleotide which has the sequence of a human Ku70 cDNA in the antisense orientation (emphasis added). Takiguchi et al. discloses a (1) a forward primer to the mouse sequence, (2) nested reverse primers to the human sequence, and (3) a cDNA probe to genomic mouse sequence (see page 130 of Takiguchi et al.). Takiguchi et al. does not, however, disclose the claimed invention. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections Under 35 U.S.C. §103(a)

In the June 26, 2006 Final Office Action, and in a February 20, 2007 Advisory Action, the Examiner rejected claim 15 as allegedly obvious over Takiguchi et al., as cited above, in combination with Reeve et al. (JBC 264(9):5047-5052 (1989)),

Milner et al. (Nat. Biotech. 15:537-541 (1997)) and in view of Au-Young et al. (U.S. 5,773,580).

In response, applicants respectfully traverse the Examiner's rejection. Applicants note that Milner et al., cited by the Examiner in the February 20, 2007 Advisory Action, discusses that the efficacy of an antisense must be tested empirically, thus indicating that the efficacy of any one antisense molecule is not predictable. Milner also states that "surprisingly few [tested] oligonucleotides gave significant heteroduplex yield", see Abstract. Applicants maintain that the claimed molecule has been empirically determined only by applicants to be efficacious as an antisense, and it is not taught or suggested by the combination of cited prior art. There is no indication that such a method could be applied to a full length antisense. Moreover, Milner, cited by the Examiner in February 20, 2007 Advisory Action as providing methods of designing and testing antisense, only discloses a method for testing antisense that are monomers up to 17-mers (e.g. see Abstract). In addition, applicants note that predictability, with respect to reasonable expectation of success, is determined at the time the invention was made (see M.P.E.P. §2143.02). In contrast to this requirement, Milner suggests that the antisense must be tested empirically, i.e. that the art is not predictable. Thus one of ordinary skill in the art would not have a reasonable expectation of success of the claimed antisense.

In addition, applicants also note that nowhere in the cited combination of references is an antisense oligonucleotide having the sequence of a human Ku70 cDNA in the antisense orientation

taught or suggested. At the most, oligonucleotides having up to 17 nucleotides (Milner et al.) or 22 nucleotides (Takiguchi et al.) are disclosed.

Accordingly, applicants maintain that the obviousness rejection is improper and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

In the June 26, 2006 Final Office Action, and in a February 20, 2007 Advisory Action, the Examiner also rejected claim 1 under 35 U.S.C. §103(a) as allegedly unpatentable over Takiguchi et al., Reeves et al., and Milner et al., the combination in view of Au-Young et al.

Applicants note that, as argued above, the efficacy of an antisense must be tested empirically, thus indicating that the efficacy of any one antisense molecule is not predictable. Applicants maintain that the claimed method recites an antisense molecule empirically determined only by applicants to be efficacious, and not taught or suggested by the combination of cited prior art. In addition, applicants note that predictability, with respect to reasonable expectation of success, is determined at the time the invention was made (see M.P.E.P. §2143.02). In contrast to this requirement, Milner et al. as cited by the Examiner, teaches that antisense must be tested empirically, i.e. that the art is not predictable. Thus, the prior art, which does not provide the antisense recited in the claimed method, does not provide a reasonable expectation of success of the claimed method.

In addition, applicants also note that nowhere in the cited combination of references is an antisense oligonucleotide having the sequence of a human Ku70 cDNA in the antisense orientation taught or suggested as recited in the claim 1 as amended.

Moreover, the method as recited in claim 1 requires that the antisense nucleic acid be enclosed in a liposome. None of the references, in combination with all of the others, teaches such *in vitro* liposome administration of the antisense oligonucleotide.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection Under 35 U.S.C. §112, First Paragraph (Written Description)

The Examiner rejected claims 1, 2, 15, 16 and 18-22 under 35 U.S.C. §112, first paragraph, as allegedly not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner indicated that the scope of the claims includes numerous variants and that the genus is highly variant because a significant number of structural differences between members of the given genus is permitted.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, and

without conceding the correctness of the Examiner's position, applicants have herein amended independent claims 1 and 15. As amended, method claim 1 recites the antisense oligonucleotide has the sequence of a human Ku70 cDNA in the antisense orientation or a human Ku80 cDNA in the antisense orientation. In addition, as amended, composition claim 15 recites the antisense oligonucleotide has the sequence of a human Ku70 cDNA in the antisense orientation. Applicants note that these antisense oligonucleotides are described in the specification at, for example, page 83, lines 7 to 16. Applicants maintain that one of skill in the *art of the claimed invention* would recognize applicants were in possession of the claimed invention at the time of filing based on description of the claimed invention in the specification. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants submit this Supplemental Information Disclosure Statement. Applicants direct the Examiner's attention to the documents which are listed on the enclosed substitute PTO-1449 form attached hereto as Exhibit A and listed hereinbelow. Documents 1 and 2 are Office Actions issued in connection with related U.S. Serial No. 10/712,642.

1. Office Action issued in connection with U.S. Application Serial No. 10/712,642; and
2. Final Office Action issued in connection with U.S.

Application Serial No. 10/712,642.

Applicants are submitting this Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(c)(4). Applicants request that the Examiner review the documents listed and make them of record in the subject application.

Conclusion

For the reasons set forth above, applicants respectfully request that the Examiner reconsider and withdraw the rejections, and solicit allowance of pending claims 1, 15, 16 and 18-22.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the total enclosed fee of $1,475.00, including a $395.00 RCE fee and a $1,080.00 fee for a five-month extension of time, is deemed necessary in connection with the filing of this Amendment and Supplemental Information Disclosure Statement. However, if any fee is required, authorization is given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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